K103810

510(k) Summary

SEP 14 2011

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 08/15/2011

1. Submitter

	Submitter
Name	KJ Meditech Co., Ltd.
Address	959-21 Daechon-dong, Buk-gu,Gwang-ju, 500-470, South Korea
Phone	+82-62-972-5476
Fax	+82-62-973-2809
Contact	Huykki Moon, CEO

2. U.S Agent/Contact Person

LK Consulting Group
951 Starbuck St. Unit J, Fullerton, CA 92833
Priscilla Juhee Chung
Phone: 714.869.3080 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

Trade Name: KJ Submerged System
Common Name: Dental Implant
Classification Name: Endosseous Dental Implant System
Product Code: DZE
Classification regulation: 21CFR872.3640

2. Predicate Device:

Bicon Implant System by Bicon LLC. (K101849, K092035, K073368, K062044, K050712, K042637, K010185, K994037, K972417)

3. Description:

The KJ Submerged System replaces the root of a missing tooth and is made from

surgical grade titanium alloy(Ti-6Al-4V) to exacting specifications. The KJ Submerged system is comprised of only two components, implant, which is the portion that goes into the jaw bone, and the abutment, which fits into the implant and provides a solid base for a crown or a denture. KJ Submerged System's locking taper provides a tight seal at the implant to abutment interface, minimizing the gap. The sloping shoulder affords felxibility at time of implant placement.

4. Indication for use:

The KJ Submerged System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading.

5. Basis for Substantial Equivalence

The KJ Submerged System has same material and indication for use and similar design and technological characteristics as the predicate devices. The KJ Submerged System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

	Subject Device	Predicate Device
510(K) Number	N / A	K101849 K092035 K073368 K062044 K050712 K042637 K010185 K994037 K972417
Device Name	KJ Submerged System	Bicon Implant System
Manufacturer	KJ Meditech Co., Ltd.	Bicon LLC.
Product Code	DZE	DZE
Indications for Use	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories
Design	Fin design Sloping shoulder Locking taper	Fin design Sloping shoulder Locking taper
Material	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	RBM Treatment and HA Coating on the fixture body No surface treatment on abutments	RBM Treatment and HA Coating on the fixture body No surface treatment on abutments

Attachments	Various abutments and components	Various abutments and components

6. Non-Clinical Testing

Testing was performed in conformance to ISO 14801 Dentistry - Implants - Dynamic fatigue tests for endosseous dental implants to ensure that the strength of the KJ Submerged System is appropriate for the intended use. Results confirmed the strength of the system.

7. Conclusion

The subject device and the predicate device have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of commercially pure titanium and have the same surface treatments. The subject and predicate device encompass the similar range of physical dimensions, including diameter and length of the implants, and diameter and height of the abutments.

Overall, KJ Submerged System has the following similarities to the predicate device:
* has the same intended use,
* uses the same operating principle,
* incorporates the same basic design,
* incorporates the same material and the surface treatment.

Based on the similarities and the test result of the fatigue test, we conclude that the KJ Submerged System is as safe and effective for its intended use and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

KJ Meditech Company, Limited
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group
951 Starbuck Street, Unit J
Fullerton, California 92833

SEP 14 2011

Re: K103810
Trade/Device Name: KJ Submerged System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 9, 2011
Received: September 13, 2011

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103810

Device Name: KJ Submerged System

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Prescription Use __√__ **AND** **Over-The Counter Use**____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEE DED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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